

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number **21-113**

MICROBIOLOGY REVIEW(S)

NOV 19 1999

REVIEW FOR HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 OF NDA 21-113
3 November 1999

A. 1. NDA 21-113 BC

APPLICANT: Bedford Laboratories
300 Northfield Road
Bedford, OH 44146

2. PRODUCT NAMES: Pamidronate Disodium, Injection
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is provided in single-dose 10 mL vials containing 3 mg/mL of the active drug ingredient.
4. METHODS OF STERILIZATION:
The product is terminally sterilized.
5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated for the treatment of moderate or severe hypercalcemia associated with malignancy, with or without bone metastases.

- B. 1. DATE OF INITIAL SUBMISSION: 26 February 1999
2. DATE OF AMENDMENT: 21 May 1999 (Subject of this Review)
3. REFERENCE LISTED PRODUCT/MANUFACTURER:
Aredia® - Novartis (see C. REMARKS, below)
4. ASSIGNED FOR REVIEW: 28 October 1999

- C. REMARKS: The drug product is compounded, filled, sealed, terminally sterilized, labeled and packaged at Ben Venue Laboratories, Inc., 300 Northfield Road, Bedford, OH.

The cited reference listed product (see B.3., above) is a lyophilized formulation. The reason for citing this product is unclear since this is a New Drug Application rather than a

Generic Application. It may be that the reference drug application (NDA 20-036) contains the clinical data that apply to this application.

This amendment provides for an additional dosage form, which is 9 mg/mL; 10 mL/vial.

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.

SP
3 November 1999

Paul Stinavage, Ph.D.
SP *11/19/99*

cc: Original NDA 21-113
HFD-510/R. Hedin/S. Markofsky
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 3 November 1999
R/D initialed by P. Cooney

**APPEARS THIS WAY
ON ORIGINAL**

THIS SECTION
WAS
DETERMINED
NOT
TO BE
RELEASABLE

1 page

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APR 14 1999

REVIEW FOR HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA 21-113
13 April 1999

A. 1. NDA 21-113

APPLICANT: Bedford Laboratories
300 Northfield Road
Bedford, OH 44146

2. PRODUCT NAMES: Pamidronate Disodium, Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:

The product is provided in single-dose 10 mL vials containing 3 mg/mL of the active drug ingredient.

4. METHODS OF STERILIZATION:

The product is terminally sterilized.

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:

The product is indicated for the treatment of moderate or severe hypercalcemia associated with malignancy, with or without bone metastases.

B. 1. DATE OF INITIAL SUBMISSION: 26 February 1999

2. DATE OF AMENDMENT: (none)

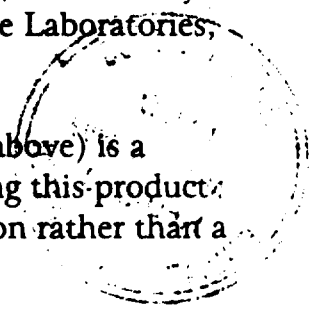
3. REFERENCE LISTED PRODUCT/MANUFACTURER:

Aredia® - Novartis (see C. REMARKS, below)

4. ASSIGNED FOR REVIEW: 31 March 1999


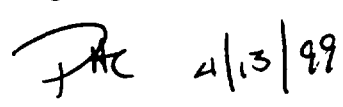
C. REMARKS: The drug product is compounded, filled, sealed, terminally sterilized, labeled and packaged at Ben Venue Laboratories, Inc., 300 Northfield Road, Bedford, OH.

The cited reference listed product (see B.3., above) is a lyophilized formulation. The reason for citing this product is unclear since this is a New Drug Application rather than a



Generic Application. It may be that the reference drug application (NDA 20-036) contains the clinical data that apply to this application.

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.


Paul Stinavage, Ph.D. 13 Apr. 1999


cc: Original NDA 21-113
HFD-510/R. Hedin/S. Markofsky
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 13 April 1999
R/D initialed by P. Cooney

**APPEARS THIS WAY
ON ORIGINAL**

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RELEASABLE

8 pages

Hedin

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION			REQUEST FOR CONSULTATION	
Division/Office) HFD-160 Attn: Peter Cooney			FROM: HFD-510	
DATE March 22, 1999	IND NO.	NDA NO. 21-113	TYPE OF DOCUMENT N	DATE OF DOCUMENT February 26, 1999
NAME OF DRUG pamidronate disodium Inj.		PRIORITY CONSIDERATION S	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE August 2, 1999
NAME OF FIRM Bedford Laboratories				
REASON FOR REQUEST				
I. GENERAL				
<input type="checkbox"/> NEW PROTOCOL <input type="checkbox"/> PRE-NDA MEETING <input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER <input type="checkbox"/> PROGRESS REPORT <input type="checkbox"/> END OF PHASE II MEETING <input type="checkbox"/> FINAL PRINTED LABELING <input type="checkbox"/> NEW CORRESPONDENCE <input type="checkbox"/> RESUBMISSION <input type="checkbox"/> LABELING REVISION <input type="checkbox"/> DRUG ADVERTISING <input type="checkbox"/> SAFETY/EFFICACY <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE <input type="checkbox"/> ADVERSE REACTION REPORT <input type="checkbox"/> PAPER NDA <input type="checkbox"/> FORMULATIVE REVIEW <input type="checkbox"/> MANUFACTURING CHANGE/ADDITION <input type="checkbox"/> CONTROL SUPPLEMENT <input type="checkbox"/> OTHER (SPECIFY BELOW) <input type="checkbox"/> MEETING PLANNED BY				
II. BIOMETRICS				
STATISTICAL EVALUATION BRANCH		STATISTICAL APPLICATION BRANCH		
<input type="checkbox"/> TYPE A OR B NDA REVIEW <input type="checkbox"/> END OF PHASE II MEETING <input type="checkbox"/> CONTROLLED STUDIES <input type="checkbox"/> PROTOCOL REVIEW <input type="checkbox"/> OTHER		<input type="checkbox"/> CHEMISTRY REVIEW <input type="checkbox"/> PHARMACOLOGY <input type="checkbox"/> BIOPHARMACEUTICS <input type="checkbox"/> OTHER		
III. BIOPHARMACEUTICS				
<input type="checkbox"/> DISSOLUTION <input type="checkbox"/> BIOAVAILABILITY STUDIES <input type="checkbox"/> PHASE IV STUDIES		<input type="checkbox"/> DEFICIENCY LETTER RESPONSE <input type="checkbox"/> PROTOCOL-BIOPHARMACEUTICS <input type="checkbox"/> IN-VIVO WAIVER REQUEST		
IV. DRUG EXPERIENCE				
<input type="checkbox"/> PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL <input type="checkbox"/> DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES <input type="checkbox"/> CASE REPORTS OF SPECIFIC REACTIONS (List below) <input type="checkbox"/> COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP		<input type="checkbox"/> REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY <input type="checkbox"/> SUMMARY OF ADVERSE EXPERIENCE <input type="checkbox"/> POISON RISK ANALYSIS		
V. SCIENTIFIC INVESTIGATIONS				
<input type="checkbox"/> CLINICAL		<input type="checkbox"/> PRECLINICAL		
COMMENTS/SPECIAL INSTRUCTIONS: Please review the attached microbiology section of a new NDA submitted by Bedford Laboratories. Dr. Sheldon Markofsky is the reviewing chemist, 827-6383. Mr. Randy Hedin is the CSO, 827-6382. cc:				
SIGNATURE OF REQUESTER		METHOD OF DELIVERY (Check one) <input type="checkbox"/> X MAIL HAND		
SIGNATURE OF RECEIVER		SIGNATURE OF DELIVERER		

Consult.074

JO:
3/31/99